

JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

The pathologist and pathology data. Hardisty JF, Presented at NCTR in Jefferson, AR on October 31, 2002.

The pathologist and pathology data. Hardisty JF. Presented at Health Canada in Ottawa, Canada on December 2, 2002.

Necropsy and histology techniques. Hardisty JF. Presented at FDA on January 9, 2003.

Current approaches to Peer Review and PWG. Hardisty JF. Presented at Battelle in Columbus, OH on June 5, 2003.

Characterization of intrathoracic mesothelioma in Fischer 344/N rats. Willson G, Clayton N, Hardisty J, and Pearse G. Presented as a poster for the Society of Toxicologic Pathology, 22nd Annual Meeting In Savannah, Georgia on June 15-19, 2003.

Transplacental carcinogenicity of azidothymidine in B6C3F1 mice and F344 rats. Walker DM, Hardisty JF, Ruecker FA, Funk KA, Wolfe MJ and Walker VE. Abstract No. 548. 2004 *Itinerary Planner*. Baltimore, MD: Society of Toxicology.

Comparison of automated software with conventional histopathology of liver step sections in an NTP Subchronic Bioassay. Willson GA, Joron TA, Lesniak D, Pearse G and Hardisty JF. Presented a poster at the STP Meeting in Salt Lake City, UT, June, 2004.

Automated Pathology Systems – Human Versus Machine Vision. Hardisty JF: Toxicology Roundtable, Augusta, MI. Sept. 2004.

Comparative hepatic toxicity: prechronic/chronic liver toxicity in rodents. Hardisty JF and Brix AE. *Toxicologic Pathology*, 33:35-40, 2005.

ACT/STP Pathology Course for Non-Pathologists. Hardisty JF. Speaker at ACT/STP Meeting, Lincolnshire, IL, May 10-13, 2005.

Defining a Noncarcinogenic Dose of Recombinant Human Parathyroid Hormone 1-84 in a 2-year study in Fischer 344 rats. Jolette J, Wilker CE, Smith SY, Doyle N, Hardisty JF, Metcalfe AJ, Marriott TB, Fox J, Wells DS. Toxicological Pathology 006;34(7):929-40.

Optimization in Pathology. Presented at RCC Scientific Workshop Basel on October 19, 2006.

Diagnostic Dilemmas in Toxicologic Pathology, Hardisty JF. Speaker, Presented at the 7th Biennial Industrial Toxicology & Pathology Short Course, Co-sponsored by the Society of Toxicologic Pathology and the University of Illinois College of Veterinary Medicine, July 23–25, 2007.

Histopathology of Hemangiosarcoma in Mice Hamsters and Liposarcomas/Fibrosarcomas in Rats Associated with PPAR Agonists. Hardisty JF, Elwell MR, Ernst H, Greaves P, Kolenda-Roberts H, Malarkey DE, Mann PC, Tellier PA. Toxicologic Pathology, 35:928-941, 2007.

General Principles in Necropsy and Histology, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.



JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS - Continued

Current Practices in Toxicologic Pathology, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.

Chronic Progressive Nephropathy and Proliferative Lesions of the Renal Tubule, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.

Histopathology of the Urinary Bladders of Cynomolgus Monkeys Treated with PPAR Agonists. Hardisty JF, Anderson DC, Brodie S, Cline JM, Hahn FF, Kolenda-Roberts H, Lele SM, Lowenstine LJ. Toxicological Pathology, 2008;36 769-776.

Ocular Collection Protocol for the Laboratory Rabbit, Dog, and Monkey. Render JA, Dubielzig RR, Dunn DG, Hardisty JF, Moore RR, Sabio DA. Presented as a poster for the 6th European Congress of Toxicologic Pathology, Edinburgh, Scotland on September 24 - 26, 2008.

"Larynx Squamous Metaplasia". A Re-consideration of Morphology and Diagnostic Approaches in Rodent Studies and its Relevance for Human Risk Assessment. Kaufmann W, Bader R, Ernst H, Harada T, Hardisty JF, Kittel B, Kölling A, Pino M, Renne R, Rittinghausen S, Schulte A, Wohrmann, T, Rosenbruch M. Presented at The 1st International ESTP Expert Workshop, Ludwigshafen, Germany; Published: Experimental and Toxicologic Pathology, 61 (2009) 591-603

Regulatory Perspective for Pathology Data. Manabe S, Oishi Y, Tamura K, Schorsch F, Weber K, Hardisty JF, Kuranami K. Panel Discussion: Presented at the 25th JSTP Annual Meeting, Hamamatsu, Japan, January 28, 2009. Published: Journal of Toxicologic Pathology 2009; 22: 209-227

Lesions in the Larynx of Wistar RccHan™: WIST Rats. Weber K, Germann PG, Iwata H, Hardisty JF, Kaufmann W, Rosenbruch M. Published: Journal of Toxicologic Pathology 2009; 22: 229-246

Thyroid Dysplasia in Wistar Hannover GALAS Rats. Weber K, Ernst R, Fankhauser H, Hardisty JF, Heider W, Stevens K. Published: Journal of Toxicologic Pathology 2009; 22: 247-254

International Prospective on Peer Review. North American Perspective presented by Hardisty JF. The 2010 Town Hall Meeting at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

Optimal Routine Sampling of the Cynomolgus Monkey Nervous System in Toxicity Studies. Hardisty JF, Moore R. Poster Presentation at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

Innumohistochemical Study of Brain Tumors in Rats Treated with Acrylonitrile. Kolenda-Roberts H, Hardisty JF. Poster Presentation at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

A Commentary on the Process of Peer Review and Pathology Data Locking. McKay JS, Barale-Thomas E, Bolon B, George C, Hardisty JF, Manabe S, Schorsch F, Terancishi M, Weber K. Published: Journal of Toxicologic Pathology 2010; 38: 508-510



JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS - Continued

Recommendations for Pathology Peer Review. Morton D, Sellers RS, Barale-Thomas E, Bolon B, George C, Hardisty JF, Irizarry A, McKay JS, Odin M, Teranishi M. Published: Journal of Toxicologic Pathology 2010; 38: 1118-1127

Pathology Working Group Review and Evaluations of Prolifer Lesions of Mammary Gland Tissues in Female Rats Fed Ammoni Perfluorooctanoate (APFO) in the diet for 2 years. Hardisty JF, Willson GA, Brown WR, McConnell EE, Frame SR, Gaylor DW, Kennedy GL, Butenhoff JL, Published: PubMed: US National Library of Medicine / National Institutes of Health. PMID: 20307141 [PubMed – indexed for MEDLINE]. Drug Chem Toxicol. 2010 Apr; 33(2): 101-137.

Industry-Contract Research Organization Pathology Interactions: A Perspective of Contract Research Organizations in Producing the Best Quality Pathology Report. Gosselin SJ,Palate B, Parker GA, Engelhardt JA, Hardisty JF, McDorman KS, Tellier PA, Silverman LR. Published: Journal of Toxicologic Pathology 2011; 000: 1-7.

JERRY F. HARDISTY, D.V.M. Chief Executive Officer Senior Pathologist

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PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. VETERINARY PATHOLOGIST

EDUCATION:

Washington University, St. Louis, Missouri, A.B., English Literature, 1966-1970 University of Missouri, St. Louis, Missouri, Pre-veterinary Studies, 1972-1974 University of Missouri, Columbia, Missouri, D.V.M., 1975-1979

CERTIFICATIONS/LICENSURE:

Certified by the American College of Veterinary Pathologists, 1984

PRESENT POSITION AND EXPERIENCE:

2007 – Present. Manager, EPL Northwest, Seattle, WA.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies from pharmaceutical, biotechnical, and agricultural clients. Offering histopathology and peer review services as well as organization of Pathology Working Groups. Provide interpretation of ultrastructural pathology. Consultation to clients on regulatory issues.

2002 - 2006. Manager, EPL Northeast, Galena, MD.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies from pharmaceutical, biotechnical, and agricultural clients. Offering histopathology and peer review services as well as organization of Pathology Working Groups. Provide interpretation of ultrastructural pathology. Consultation to clients on regulatory issues.

2000 – 2002. On-Site Consultant, DuPont Pharmaceuticals Company, Wilmington, DE.

Full-time, on-site consultant to DuPont Pharmaceuticals Company. Provided necropsy supervision and microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies by DuPont Pharmaceuticals Company.



1999 – 2000. Senior Projects Manager, Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies for both commercial clients and the National Toxicology Program's Pathology Quality Assessment Program and the NTP Archives.

1994 – 1999. Director and Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Responsible for project management, direction and technical supervision of the North Carolina Branch of EPL. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies. Provided support to the National Toxicology Program's Pathology Quality Assessment Program and the NTP Archives.

1990 – 1994. Veterinary Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Duties included histopathologic interpretation of tissues from various laboratory animals used for toxicology and carcinogenesis studies.

1989 – 1990.	Pathologist, EPL Scientific Limited, Harrogate, England.
1985· 1989.	Veterinary Pathologist, ICI Pharmaceuticals, Division of ICI Americas, Wilmington, Delaware.
1982 – 1989.	Staff Pathologist, Brandywine Zoo, Wilmington, Delaware.
1982 – 1985.	Senior Lecturer, Department of Pathobiology, University of Pennsylvania School of Veterinary Medicine.
1979 – 1982.	Resident in Pathology, National Zoological Park, Washington, DC.



1974 - 1975.

Food Technologist, Pet Foods Department, Grocery

R&D, Ralston Purina Co., St. Louis, MO.

1970 - 1971.

Secondary School Teacher, St. Louis, MO.

PROFESSIONAL MEMBERSHIPS:

American Veterinary Medical Association
American College of Veterinary Pathology
Society of Toxicological Pathology
British Society of Toxicologic Pathologists
C.L. Davis Foundation for the Advancement of Veterinary
Pathology
North Carolina Society of Toxicology

SERVICE TO PROFESSIONAL ASSOCIATIONS:

Chairman, STP Nomenclature Subcommittee on the Mammary Gland

Member, STP Nomenclature Subcommittee on the Respiratory System

Adjunct Associate Professor at the School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology

Member, STP Symposium Committee, 1995-1998

Co-Chairman, STP Educational Committee, 1996

Chairman, STP Symposium Committee, 1998

Copy Editor, C.L. Davis Foundation Newsletter, 1998

Member, Advisory Board, C.L. Davis Foundation for the Advancement of Veterinary Pathology, 2000-2004

Member, Executive Committee, Society of Toxicologic Pathology, 2000-2004

Chairman, STP Journal Committee, 2005

Chair, Global Editorial Steering Committee, 2006-2008

President-Elect, Society of Toxicologic Pathology, 2008-2009

President, Society of Toxicologic Pathology, 2009-2010

Member, ILSI/HESI Subcommittee on Distinguishing Adverse from Adaptive.

Non-Functional, and Pharmacologic Changes in Toxicology Studies, 2009-2010

SERVICE TO EDITORIAL BOARDS OF SCHOLARY JOURNALS:

Reviewer for Toxicologic Pathology, 1998-2002



PROFESSIONAL DEVELOPMENT/SPECIALIZED TRAINING:

Educational Activitien 1981	es/Special Lectures: Diseases of zoo mammals and birds. Pathology of Laboratory Animals, Washington, D.C.
1982	Pathology of zoo animals. Friends of the National Zoo, Washington, D.C.
1982	Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in small animal pathology rotation.
1982-1985	Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in large animal pathology rotation.
1983	University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals.
1983-1984	Philadelphia College of Pharmacy and Science. Principles of Pathology.
1983-1984	University of Pennsylvania School of Veterinary Medicine, Course 5001, General Endocrine Pathology.
1983	University of Pennsylvania School of Veterinary Medicine, Course 4501, Infectious Diseases of Dogs and Cats, Neuroendocrine Pathology.
1984	University of Pennsylvania School of Veterinary Medicine, Course 5401, Infectious Diseases of Dogs and Cats.
1984	University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals, Diseases of Horses.
1985	University of Pennsylvania School of Veterinary Medicine, Course 5402, Diseases of Horses.
1996	School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular.



	1997	School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular.
	1999	Chemical Industry Institute of Toxicology, Pathology Short Course for Toxicologists. Necropsy and Histology Techniques. Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays.
•	2002	Society of Toxicology, Continuing Education Course: Blood and Lymphoid Tissue: Neoplasia of Blood and Lymphoid Tissue.
	2003	Society of Toxicology, Continuing Education Course: Integrating Toxicologic Pathology into Compound Evaluation and Risk Assessment II: Diagnostic Drift.
	2006	International Institute of Biotechnology and Toxicology. Chennai, Tamal Nadu, India: Regulatory Toxicologic Pathology
	2007	School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine The Use of Genetically-Modified-Mice in Toxicology
	2008	Beijing Pharma and Biotech Center (BPBC) – Sino American Pharmaceutical Professionals Association (SAPA) Beijing Workshop: Toxicologic Pathology in New Product Development. Fundamentals of General and Toxicologic Pathology and Histopathology of the Respiratory System: Nose, Larynx and Lungs.
	2010	School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine, The Use of Genetically-Modified-Mice in Toxicology and Trust me, I'm a Pathologist.
		National Institute for the Control of Pharmaceuticals and Biological Products and the Society of Toxicologic Pathology: USA-China Carcinogenicity Studies Workshop. Beijing, China. Reading the

Rodent Bioassay: Problems, Pitfalls and Peer Review and Common Background Tumors of Laboratory Rodents.



Seminars and Presentations:

Canine parvovirus. Johns Hopkins Division of Comparative Medicine, Baltimore, 1980.

Parvo-like enteritis in golden lion tamarins. Primate Pathology Workshop, New Orleans, 1980.

Canine parvovirus in South American canids. American Association of Zoo Veterinarians, Washington, D.C., 1980.

Leiomyomas of the genital tract in large zoo mammals. International Academy of Pathology, Chicago, 1981.

Respiratory distress syndrome in neonatal reindeer (poster). International Academy of Pathology, Chicago, 1981.

Herpesvirus infections in old world primates. Johns Hopkins Division of Comparative Medicine, Baltimore, 1981.

Selected diseases of zoo animals. University of Pennsylvania School of Veterinary Medicine, Philadelphia, 1981.

Tuberculous osteomyelitis in captive marsupials (poster). International Academy of Pathology, Boston, 1982.

Selected diseases of zoo animals. Virginia-Maryland Regional College of Veterinary Medicine, Blacksburg, 1982.

Post mortem examination as a technique in research. Symposium on the effects of oil on birds, Stone Harbour, 1982.

Enzootic nasal tumors in sheep. Pennsylvania Diagnostic Workshop, Harrisburg, 1983.

Gross pathology of zoo animals. Eighth Annual C.L. Davis Conference in Veterinary Pathology, Philadelphia, 1984.

Peer review from the perspective of a consultant pathologist. Society for Quality Assurance Annual Meeting, Phoenix, Arizona, 1995.

Lesions of Dioxin in laboratory animals. Society of Toxicologic Pathologists 15th International Symposium, St. Louis, Missouri, 1996.



Use of genetically altered mice in short-term bioassays. The 22nd Annual C.L. Davis DVM Foundation Continuing Education Symposium, North Carolina State University, College of Veterinary Medicine, Raleigh, North Carolina, June 14-18, 1998.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. Pathology of Genetically-Engineered Mice, National Institution of Health, Bethesda, Maryland, February 24-25, 1999.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. CL Davis Foundation European Pathology Division Symposium, Nantes, France, July 1999.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. Wyeth Ayerst Research, Chazy, NY, November 1999.

Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models, sponsored by the CL Davis Foundation, Houston, TX, February 17-19, 2000.

Pathology Peer Review: Current Concepts. Society of Quality Assurance, 16th Annual Meeting, Montreal, Canada, October 9-13, 2000.

Background pathology of genetically-engineered mouse lines. American College of Toxicology, 21st Annual Meeting, San Diego, CA, November 13, 2000.

Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models sponsored by the CL Davis Foundation, Houston, TX, February 15-17, 2001.

Pathology of Transgenic Mice. CL Davis Foundation European Division Pathology Symposium (Szent Istvan University, Budapest, Hungary), July 5-7, 2001.

Genetically-engineered mice in toxicology. Pathology of Mutant Animal Models, sponsored by the CL Davis Foundation, Houston, TX, February 13-16, 2002.

Necropsy and Histology: Current Practices in Pathology. Health Canada, Existing Substances Branch, Ottawa, Canada, March 2002.

Pathology Data and Tox-Path Issues. USFDA, May 20, 2002.



Necropsy and Histology, Current Practices in Pathology, Pathology of Transgenic Mice, Diagnostic Drift. May 21-22, 2003. Health Canada, Ottawa, Canada.

Necropsy and Histology, Current Practices in Pathology, Pathology of Transgenic Mice, Diagnostic Drift. December 2-3, 2003. Health Canada, Ottawa, Canada.

Diagnostic Dilemmas. Industrial and Toxicologic Pathology Course VI. Chicago, IL, July 18-21, 2004.

Pathology of p53 heterozygous Transgenic Mice, CL Davis Foundation, Northeast Division Meeting, December 10, 2004, Nutley NJ.

Pathology of Transgenic Mice. Korean Society of Toxicology. 2004 Annual Meeting, November 4-5, 2004, Seoul, S. Korea.

Current Practices in Pathology, Peer Review. Korean Institute of Toxicology, November 8, 2004, Daejong, S. Korea.

The PTOX Seminar Series: Transgenic Models. Forest Research Institute, October 21, 2004, Jersey City, NJ.

An Introduction to Toxicologic Pathology, Adolor Corporation, March 4, 2005, Exton, PA.

Adverse vs Non-Adverse Lesions in Toxicology Studies. Korean Institute of Toxicology, June 1, 2005, Daejong, South Korea.

Overview of Neoplastic Lesions in Rodents. Korean Association for Laboratory Animal Science, 21st International Symposium, June 3, 2005, Seoul, South Korea.

Module 3: Carcinogenesis. Alternative Onco Study Models – Update, Lecture and Practical. British Society of Toxicologic Pathlogy, Modular Education Programme in Toxicologic Pathology, July 15, 2005, Edinburgh, Scotland.

Transgenic Mice: Creation, Pathology and Use in Toxicology Studies. CL Davis Foundation European Division, Annual Meeting, September 6, 2005, Naples, Italy.

The Rodent Biossay in the 21st Century: Reading the Study – Problems, Pitfalls and Peer Review. CL Davis Foundation, NorthEast Division, November 11, 2005, Nutley, NJ.

INHAND and the GESC – the New Nomenclature Project. Japanese Society of Toxicologic Pathology, February 7, 2008, Nagoya, Japan



Pathology of Transgenic Mice. DIMS Institute of Medical Science, February 8, 2008, Ichinomiya, Japan

Trust Me, I'm a Pathologist. American College of Toxicology, Palm Springs, November 1, 2009, Palm Springs, CA.

PUBLICATIONS AND PRESENTATIONS:

Books:

Mann, P.C.: How to Buy a Used Car Without Getting Gypped. New York, New York, Harper and Row, 1975.

Book Chapters:

Salivary, Harderian and Lacrimal Glands, by S. Botts, M.P. Jokinen, E.T. Gaillard, M.R. Elwell, and P.C. Mann. In: <u>Pathology of the Mouse</u> (R.R. Maronpot, G.A. Boorman, and B.W. Gaul, eds), Vienna, IL, Cache River Press, 1999.

Thymus, Spleen and Lymph Nodes, by J.M. Ward, P.C. Mann, H. Morishima, and C.H. Frith. In: <u>Pathology of the Mouse</u> (R.R. Maronpot, G.A. Boorman, and B.W. Gaul, eds), Vienna, IL, Cache River Press, 1999.

Managing Pitfalls in Toxicologic Pathology, by P.C. Mann, J.F. Hardisty, and M.D. Parker. In: <u>Handbook of Toxicologic Pathology</u> (W.M. Haschek, C.G. Rousseaux, and M.A. Wallig, eds), San Diego, CA, Academic Press, 2002.

Principles of Pathology for Toxicology Studies by Steven R. Frame and Peter C. Mann. In; <u>Principles and Methods of Toxicology, Fifth Edition</u> (A. Wallace Hayes, ed), Boca Raton, FL, CRC Press, 2008

Abstracts:

Mann, P.C., Bush, M., Jones, D.M., Griner, L.A., Keuhne, G.R. and Montali, R.J.: Leiomyomas of the genital tract in large zoo mammals. Laboratory Investigation, 1981, 44:40A.

Mann, P.C., Montali, R.J. and Bush, M.: Respiratory distress syndrome in neonatal reindeer. Laboratory Investigation, 1981, 44:40A-41A.

Mann, P.C., Montali, R.J. and Bush, M.: Tuberculous osteomyelitis in captive marsupials. Laboratory Investigation, 1982, 46-51A.

Harrison, I., Tulleners, E., Mann, P.C. and Raker, C.W.: Assessment of partial arytenoidectomy without mucosal closure of the horse. Vet. Surgery, 1986, 15:122.



Mahler, J.F., Mann, P., Takaoka, M. and Maronpot. R.: Spontaneous lesions of the FVB/N mouse. Tox. Path., 23(6), 1996, 744-745.

Torrey CE, Allen JS, Selinger K, Mann P, Miller RT and Rickert DE. Testing of Clofibrate in a 6-Month Gavage Study Using p53[±] Mice. Toxicologic Pathology 29S:205-207, 2001.

Jackson, K., Okasaki, K., Chihaya, Y., Sato, K., Koelling, M., Meyer, S., and Mann, P. Results of a validation carcinogenicity study using transgenic p53 +/- and transgenic ras H2 mice. The Japanese Society of Toxicology, 2004 Annual Meeting, July 2004.

Acute Adverse Effects of the Indenopyridine, CDB-4022 (Racemate), on the Ultrastructure of Sertoli Cells, Spermatocytes, and Spermatids in the Testes of Treated Rats: Comparison to the Known Sertoli Cell Toxicant, Di-n-Pentylphthalate (DPP), 38th Annual Meeting, Society for the Study of Reproduction, July 24-27, 2005, Quebec City, Quebec, Canada.

Scientific Papers:

Wagner, J.E. and Mann, P.C.: Botulism in California sea lions (Zalophus californianus), a case report. Journal of Zoo Animal Medicine, 1978, 9:142-145.

Kier, A.B., Mann, P.C. and Wagner, J.E.: Disseminated sporotrichosis in a cat. JAVMA, 1979, 175:202-204.

Taylor, J.L., Wagner, J.E., Kusewitt, D.F. and Mann, P.C.: Klossiella parasites of animals. A literature review. Veterinary Parasitology, 1979, 5:137-144.

Wagner, J.E., Burton, C.H., Morehouse, L.G. and Mann, P.C.: A computerized system for retrieval of case information in a veterinary diagnostic laboratory. American Journal of Veterinary Research, 1979, 40:336-442.

Mann, P.C., Bush, M., Appel, M.J.G., Beehler, B.A. and Montali, R.J.: Canine parvovirus infection in South American canids. JAVMA, 1980, 177:779-783.

Wightman, S.R., Mann, P.C. and Wagner, J.E.: Dihydrostreptomycin toxicity in the Mongolian gerbil. Lab. Animal Science, 1980, 30:71-75.

Montali, R.J. and Mann, P.C.: Selected diseases of zoo animals. C.L. Davis Foundation, Training Aid Issue, 1981, Vol. XI.

Montali, R.J., Mann, P.C. and Seidensticker, J.: Rabies in raccoons - Virginia. Morbidity and Mortality Weekly Report, 1981, 30:353-355.



Mann, P.C., Bush, M., Janssen, D.L. Frank, E.S. and Montali, R.J.; Clinopathologic correlations of tuberculosis in large zoo mammals. JAVMA, 1981, 179:1123-1129.

Montali, R.J., Mann, P.C., Jones, D.M., Griner, L.A., Keuhne, G.R., Narushima, E. and Bush, M.: Leiomyomas in the genital tract of large zoo mammals.

Proceedings XXIV International Symposium on the Disease of Zoo Animals, 1982, Vesprem, 117-122.

Mann, P.C., Montali, R.J. and Bush, M.: Mycobacterial osteomyelitis in captive marsupials. JAVMA, 1982. 181:1331-1333.

Acland, H.M., Mann, P.C., Robertson, J.L., Divers, T.J., Lictensteiger, C.A. and Whitlock, R.H.: Toxic hepatopathy in neonatal foals. Vet Path, 1984, 21:3-9.

Reef, V.B., Mann, P.C. and Orsini, P.G.: Echocardiographic detection of tricuspid atresia in two foals. JAVMA, 1987, 191:225-228.

Morris, C.F., Robertson, J.L., Mann, P.C., Clark, S. and Divers, T.J.: Hemolytic uremic-like syndrome in two horses. JAVMA, 1987, 191:1453-1454.

Tulleners, E.P., Harrison, I.W., Mann, P.C. and Raker, C.W.: Partial arytenoidectomy in the horse with and without mucosal closure. Vet Surgery, 1988, 17:252-257.

Orsini, PG, Raker CW, Reid CF, Mann P. Xeroradiographic evaluation of the equine larynx, Am J Vet Res. 1989, 50(6):845-9.

Tulleners, E., Mann, P., Raker, C.W., Epiglottic augmentation in the horse. Vet. Surgery, 1990, 19:181-190.

Bader, R., Gembardt, C., Kaufmann, W., Kuttler, K., Mann, P.C., Van Zwieten, M.J. and Zurcher, C.: Part I: The Rat, 5. Integumentary System. In: International Classification of Rodent Tumours, (U. Mohr, ed), pp 1-45. International Agency for Research on Cancer, 1993.

Hayes, J.R., Wilson, N.H., Roblin, M.C., Mann, P.C. and Kiorpes, A.L.: 28-Day continuous dosing study in minipigs with a SALATRIM structured triacylglycerol composed of stearate, acetate, and propionate. J. Agric. Food Chem., 1994, 42:563-571.



Dodd, D.E., Stuart, B.O., Rothenberg, S.J., Kershaw, M., Mann, P.C., James, J.T. and Lam, C.: Acute, 2-Week, and 13-Week Inhalation Toxicity Studies on Dimethylethoxysilane Vapor in Fischer 344 Rats. Inhalation Toxicology, 6:151-166, 1994.

Malarkey, D.E., Devereux, T.R., Dinse, G.E., Mann, P.C. and Maronpot, R.R.: hepatocarcinogenicity of chlordane in B6C3F1 and B6D2F1 male mice: evidence for regression in B6C3F1 mice and carcinogenesis independent of *ras* proto-oncogene activation. Carcinogenesis, Vol. 16, No. 11, 2617-2625, 1995.

Mann, P.C., Boorman, G.A., Lollini, L.O., McMartin, D.N. and Goodman, D.G. Proliferative lesions of the mammary gland in rats, IS-2. In: Guides for Toxicologic Pathology, STP/ARP/AFIP, Washington, D.C., 1996.

Mann, P.C. Pathology peer review from the perspective of an external peer review pathologist. Toxicologic Pathology ISSN: 0192-6233, Vol. 24, No. 5, 650-653, 1996.

Mahler, J.F., Stokes, W., Mann, P.C., Takaoka, M. and Maronpot, R. Spontaneous lesions in aging FVB/N mice. Toxicologic Pathology ISSN: 0192-6233, Vol. 24, No. 6, 710-716, 1996.

Mann, P.C., Selected lesions of dioxin in laboratory rodents. Toxicologic Pathology ISSN: 0192-6233, Vol. 25, No. 1, 72-79, 1997.

Gray, L.E., Wolf, C., Mann, P., Ostby, J.S., In utero exposure to low doses of 2,3,7,8-tetrachlorodibenzo-p-dioxin alters reproductive development of female Long Evans hooded rat offspring. Toxicology and Applied Pharmacology, Vol 146, No. 2, 237-44, 1997.

Eckhoff G, Mann P, Gaillard E, Dykstra M, Swanson G. Naturally Developing Virus-Induced Lethal Pneumonia in Two Guinea Pigs (Cavia porcellus). Contemp Top Lab Anim Sci, 1998, 37(1):54-57.

Burns-Naas, L.A., Mast, R.W., Klykken, P.C., McCay, J.A., White, K.L., Mann, P.C. and Naas, D.J., Toxicology and humoral immunity assessment of decamethylcyclo-pentasiloxane (D_5) following a 1-month whole body inhalation exposure in Fischer 344 rats. Toxicological Sciences, 43:28-38, 1998.

Burns-Naas, L.A., Mast, R.W., Meeks, R.G., Mann, P.C. and Thevenaz, P., Inhalation toxicology of decamethylcyclo-pentasiloxane (D_5) following a 3-month nose-only exposure in Fischer 344 rats. Toxicological Sciences, 43:230-240, 1998.



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PETER C. MANN, D.V.M Diplomate, A.C.V.P.

APRIL 23, 2010

Date

JAMES B. NOLD

Biotechnics

Formal Education:

1985 Colorado State University

Fort Collins, CO PhD Pathology

1980 The Armed Forces Institute of Pathology

Washington, DC

Pathology Residency Diploma

1973 Ohio State University

Columbus, OH

DVM

Board Certifications and Licensure:

Diplomate, American College of Veterinary Pathologists, 1980

Professional Experience:

WIL Research Laboratories, LLC/Biotechnics

Hillsborough, NC

02/09/09 - Present

Position: Senior Pathologist

Pathology

Performs microscopic examination of material obtained from various in-house studies utilizing different species. These will include acute, subacute and chronic studies. Records the microscopic findings in the on-line computer system utilizing the pathology master list of terms or microscopic lesions established for the given species or organ. Correlates the clinical pathology data with the microscopic observations. Writes the pathology summary, which includes organ weight, gross, microscopic and clinical pathology interpretations on various studies. Provides consultation to the necropsy group during the examination of individual animals sacrificed or which died on study. Provides direction and professional consultation for the department during the absence of the Director. Scientific and technical adviser for necropsy and histology labs. Maintains professional level of expertise by attending scientific meetings,

Professional Experience (Continued):

reading appropriate professional journals, and participating in professional organizations. Special interests in neuropathology include brain morphometry in developmental toxicity studies. Assists with the clinical care of study animals.

GlaxoSmithKline Research Triangle Park, NC

2003 - 2009

Position: Director of Morphologic Pathology

Safety Assessment, Pathology

Directed the histology and necropsy service function and supervised the Manager of Necropsy and Laboratory Services. Managed the contracted histopathology workload and assisted in scheduling and assignment of studies. Provided pathology support to both research and development functions, including consultation and collaboration on target and chemical class liability, animal model selection, and investigative and regulatory study design, as well as gross, microscopic and molecular pathologic evaluation and data interpretation of target localization and biological profiling, investigational, and regulatory studies.

2001 - 2003

<u>Position</u>: Director of Regulatory & Discovery Pathology Safety Assessment, Pathology

Provided pathology support to both research and development functions, including consultation and collaboration on target and chemical class liability, animal model selection, and investigative and regulatory study design, as well as gross, microscopic and molecular pathologic evaluation and data interpretation of target localization and biological profiling, investigational, and regulatory studies.

Pathology Associates A Charles River Company Durham, NC

1997 - 2001

Position: Division Director

Was responsible for the overall operation of the North Carolina Division for Pathology Associates – A Charles River Company. Served as the senior administrator of the group and directly

Professional Experience (Continued):

supervises five doctorate level scientists and the Division Director. Served as a study pathologist and as a business development representative for the organization. Specialized in general toxicologic pathology and electron microscopy. The North Carolina Division currently has a staff of 20 personnel.

Covance Laboratories, Inc. Pathology Department Madison, WI

1993 - 1996

Position: Director of Pathology

Responsible for all administrative functions of the department and for the scientific direction of the Anatomical Pathology Section (which includes necropsy and histology) and the Clinical Pathology Section (which includes hematology and clinical chemistry). Directly supervised five anatomical pathologists, one clinical pathologist, the section supervisors of the Anatomic Pathology Section, and an administrative assistant. Also served as a study pathologist. Special interests in morphometry, immunopathology, and general toxicologic pathology.

Corning Hazleton, Inc. Pathology Department Madison, WI

1990 - 1993

Position: Pathologist

Study pathologist for acute, subchronic, chronic, and reproductive toxicology, and oncogenicity studies using rats, mice, dogs, rabbits, nonhuman primates, and domestic livestock as the experimental animals. Supervised the macroscopic examination of the test animals, evaluated the prepared tissues, and wrote the pathology portion of the study reports.

Specialized in morphometry and immunohistochemistry techniques. Radiation pathology, immunopathology, and acute toxicologic pathology were particular areas of interest.

Articles:

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Vigneulle, R.M.; Herrera, J.; Gage, T.; Sellitti, D.; MacVittie, T.J.; Mohaupt, T.; Heman-Ackah, L.M.; Nold, J.B.; Dubois, A. Function of intestinal mucosa in dogs following irradiation utilizing an isoperistaltic ileostomy. *Federation Proceedings* **1987**, *46*, 4447A.

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Miller, G.K.; Benjamin, S.A.; Nold, J.B. Developmental injury, postnatal immune function, and lymphoproliferative neoplasia in the dog. *Proceedings* **1986**, 123.

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Miller, G.K.; Nold, J.B.; Benjamin, S.A. Prenatal and neonatal radiation injury and immunologic development. *Laboratory Investigation* **1986**, *54*, 43A.

James B. Nold	CURRICULUM VITAE
Page 9	

Date

James B. Nold



ROBERT R. MARONPOT SENIOR PATHOLOGIST

EDUCATION:

Michigan State University, B.S., 1963 Michigan State University, D.V.M., 1965 Michigan State University, M.S., 1966 Harvard University, M.P.H., 1972

PRESENT POSITION AND BACKGROUND:

2008 – Present	Senior Pathologist, Experimental Pathology Laboratories, Inc. Research Triangle Park, NC
2007 - Present	Maronpot Consulting, LLC, 1612 Medfield Road Raleigh, NC
1992 - 2006	Chief, Laboratory of Experimental Pathology, Environmental Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1991 - 1992	Chief, Experimental Toxicology Branch, National Toxicology Program National Institute of Environmental Health Sciences, Research Triangle Park, NC
1990 - 1991	Head, Cancer Genetics & Molecular Pathology, Experimental Carcinogenesis & Mutagenesis Branch, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1989 - 1993	Board of Directors, American Board of Toxicology, Washington, D.C. University of North Carolina, Chapel Hill, N.C.
1981 - 1990	Head, Experimental Pathology, Chemical Pathology Branch, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1978 - 1981	Senior Fellow, Bushy Run Research Center, Carnegie-Mellon University 4400 Fifth Avenue, Pittsburg, Pennsylvania
1975 - 1978	Head, Pathology Department, Chemical Hygiene Fellowship, Carnegie-Mellon Institute of Research, 4400 Fifth Avenue, Pittsburg, Pennsylvania
1974 - 1975	Head, Research Animal Facility
1974 - 1975	Acting Head, Experimental Pathology Division, Naylor Dana Institute for Disease Prevention, American Health Foundation, Valhalla, New York



PRESENT POSITION 1974 - 1975	I AND BACKGROUND: – Continued Clinical Assistant Professor of Pathology, New York Medical College, Valhalla, New York
1975	Consultant in Veterinary Pathology, Memorial Sloan-Kettering Cancer Research Center, New York, New York
1972 - 1974	Research Fellow in Comparative Pathology, Pathology Department, Harvard Medical School and Angell Memorial Animal Hospital Boston, Massachusetts
1971 - 1972	Research Fellow in Public Health, Microbiology Department, Harvard School of Public Health, Boston Massachusetts Valhalla, New York
1968 - 1971	Head, Veterinary Medicine Department, U.S. Naval Medical Research Unit #3 Cairo, Egypt
1966 - 1968	Veterinary Laboratory Officer, Veterinary Corps, U.S. Army Pathology Division, U.S. Army Medical Research and Nutrition Laboratory, Denver, Colorado
1965 - 1966	NIH Postdoctoral Fellow, Pathology Department, Michigan State University, East Lansing, Michigan

PROFESSIONAL MEMBERSHIPS:

American College of Veterinary Pathologists

Society of Toxicologic Pathologists

Society of Toxicology

SPECIALTY BOARDS & HONORS:

Diplomate, American College of Veterinary Pathologists, 1973

Diplomate, American Board of Toxicology, 1980

Distinguished Postdoctoral Veterinary Alumnus Award from

Michigan State University College of Veterinary Medicine - 2000

President, Society of Toxicologic Pathology - 2001-2002

Editor-in-Chief, Toxicologic Pathology - 2001-2004



SELECTED NATIONAL & INTERNATIONAL INVITED PRESENTATIONS SINCE 2007:

2007 Lectures

Society of Toxicology Annual Meeting
 Charlotte, NC – March 2007
 Lectured at a Continuing Education Course
 Rodent Imaging Overview for the Toxicologist
 "Magnetic Resonance Imaging"

7th Biennial Industrial Toxicology & Pathology Short Course

University of Illinois – July 2007 "Carcinogenicity Assessment"

and

"Application of Multimodality Imaging in Toxicologic Pathology"

American Association for Laboratory Animal Science Annual Meeting

Charlotte, NC – October 2007

The Wallace P. Rowe Lecture

"The Cancer Bioassay: Challenges for the Future"

and

Seminar on Current Imaging Modalities for Rodent Xenograft Models "MRI Imaging Systems"

National Academy of Science Workshop on Mouse Liver Tumors

Washington, DC – November 2007 "Mouse Models for Carcinogenicity"

American College of Veterinary Pathologists

Savannah, Georgia - November 2007

Lectured at a Continuing Education Course

Rodent Imaging Overview for the Pathologist

"Magnetic Resonance Imaging"

2008 Lectures

ILSI Annual Meeting

Rio Grande, Puerto Rico - January 2008

Organized symposium on "Applications of Small Animal Imaging in Toxicology Research and Testing"

Lectured on "Application of Magnetic Resonance Imaging in Toxicology and Toxicologic Pathology"

NIEHS

February 2008

Lecture on "Comparative Medicine Branch Pathology/Case Presentations"

Aperio Research Triangle Park Digital Pathology Seminar

May 13, 2008

Lecture on "Digital Pathology for Peer Review and Phenotyping"



SELECTED NATIONAL & INTERNATIONAL INVITED PRESENTATIONS SINCE 2007: Continued

 NTP Satellite Symposium, STP Annual meeting Conundrums in Toxicologic Pathology June 21, 2008, San Francisco

· 2nd East Mediterranean ICLAS Regional Meeting

"Overview of Imaging Modalities and Control of Small Animal Physiology During Live Imaging" and "Application of MRI in Toxicology and Toxicologic Pathology" Jerusalem, Israel, December 3-4, 2008.

TEVA Pharmaceutical Company, Israel
 "The Cancer Bioassay: Past, Present, Future"
 December 8, 2008

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